

Product Responsibility Best Practices	SUBJECT Technical Files and Record Keeping (United States)		LAST UPDATE July 2018
	APPLIES TO • Suppliers • Distributors	FOCUS ON How to maintain a comprehensive collection of all paperwork associated with a robust compliance program.	
	QUICK LINKS • PPAI Corporate Responsibility: http://ppai.org/corporate-responsibility • Consumer Product Safety Commission: www.cpsc.gov		Intended for intermediate compliance programs

Italic grey text indicates a hyperlink listed in the Online Resources section of this document.

Regulations

A technical file is a comprehensive collection of information and documents detailing nearly everything about your product. Documentation should include details about the design, manufacture and operation of a product, as well as compliance documentation.

There are many regulations that require various forms of document retention. Here we will focus on the recordkeeping requirements for the technical file required under the *United States Consumer Product Safety Commission's (CPSC) Reasonable Testing Program*. Toys and children's products are among the many categories that require technical file documentation in both the United States and Europe.

U.S. recordkeeping requirements are based on *section 1107.26* of the *Consumer Product Safety Improvement Act (CPSIA)*, and the "reasonable testing program" is the basis for the *Certificate of Compliance* – whether it is the *General Certificate of Conformity (GCC)* or the *Children's Product Certificate (CPC)* in 16 CFR 1107.

The primary purpose of this federal regulation, as required by the CPSIA, is to establish the protocols and standards for ensuring continued testing of children's products periodically and the continued compliance of these children's products. The regulation also includes testing requirements when there has been a *material change*, a voluntary consumer product labeling program, and a requirement for the manufacturer to safeguard against the exercise of *undue influence on a third party conformity assessment body*.

Requirements For A Reasonable Testing Program

The reasonable testing program requirements for certification of children's products are divided into five sections.

1. General Requirements (*1107.20*) – Test requirements enable one to certify that a product complies with applicable rules, bans, standards, and regulations.
2. Periodic Testing (*1107.21*) – Protocol requirements for testing.
3. Material Change (*1107.23*) – Changes that a manufacturer makes to a product's design, manufacturing process, equipment and tooling, source of component parts, etc., which could affect the ability for a product to comply with applicable children's product safety standards.
4. Undue Influence (*1107.24*) – Avoid compromising the integrity of product testing processes or results.
5. Recordkeeping (*1107.26*) – Requirements for documentation demonstrating compliance.

The children's product manufacturer must maintain various records for each product. These include:

1. Copy of the *CPC* for each product
2. Records of each *third party certification test* (separate CPCs and test records required for each manufacturing site)
3. Records of appropriate *periodic tests*. Periodic test plan and periodic results for each product, production testing plan, and results.
4. Descriptions of all *material changes* in product design, manufacturing process, sourcing of component parts, and the certification tests and results associated with these material changes.

5. Records of the *undue influence* procedures, including training materials and records for a period of 5 years. They must be made available to the CPSC upon request, either in hard copy or electronically.

Product Certification

Upon successful completion of the certification testing, a CPC is to be issued by the manufacturer that is the importer of record for product manufactured outside of the U.S., or by the domestic manufacturer.

The product certification rule pertaining to testing and labeling requires that all manufacturers of children's products must conduct periodic testing. This periodic testing must be performed by a CPSC-accepted third party laboratory at the appropriate intervals.

A list of the *CPSC-accepted laboratories* is available on the CPSC website.

Note: The labs are accepted individually to each specific test, and it is therefore important to know which tests a lab is accepted to perform, not simply that they are included on CPSC's list. Ideally choose a lab that is accredited to all of the tests that are applicable to your product.

Periodic Testing Plan

The manufacturer must develop and document the periodic testing plan to provide a high degree of assurance that the children's products manufactured after the issuance of the CPC continue to comply with all applicable children's product safety rules. This periodic testing plan must include the tests to be conducted, the intervals at which the tests will be conducted, and the number of samples tested.

Example: A manufacturer may perform mechanical use and abuse testing on 12 samples for every 100,000 pieces produced for an assembled toy, but it may determine that chemical testing is needed only on an annual basis as they buy bulk paint and plastic and have certified compliance. This type of detail is what is needed in the documented periodic testing plan.

Production Testing Plan

A production testing plan is a voluntary testing plan that describes the production management techniques and tests that are performed on the product. This plan will identify all tests required, although not necessarily using the specific test methods used for certification testing. The plan will also include reference to all recurring testing.

Production testing plans may also incorporate the use of process management techniques, such as control charts, statistical process control programs, or failure modes and effects analyses.

The process management techniques should be used to control potential variations in product manufacturing that could ultimately affect the product's ability to comply with applicable children's product safety rules.

The plan will detail the tests to be conducted and the measurements to be taken. In addition, the plan will specify the intervals at which these tests or measurements will be made, along with the number of samples that must be evaluated. There must be a production testing plan specific to each manufacturing site (factory) and each children's product produced at each site.

- The production testing plan must include the basis for determining that it provides that needed high degree of assurance of continued compliance.

As noted previously, a production testing plan is not mandatory, and periodic testing can be performed annually without a formal documented production testing plan. A factory quality control (QC) plan typically includes much of the production testing plan requirements. Any factory should have internal quality controls to ensure consistent production. A QC plan often includes steps that address incoming material controls, molding machine parameters, sharp tool controls, assembly process plans, and many others. If a manufacturer is relying on a production testing plan to reduce the frequency of periodic testing, the manufacturer must use "due care" to assess the adequacy of the production testing plan. It is not enough to simply review the plan; the manufacturer should obtain some evidence that the plan is actually being implemented and is effective. This additional verification may include a factory visit by the manufacturer or their representative, verification of test reports, and/or additional sampling of products for correlation testing.

Material Change

If a children's product undergoes a material change, additional testing may be required to confirm continued compliance.

A material change may include a change in:

- Product design—including all component parts, their composition, and their interaction and functionality when assembled
- Manufacturing process—for example, moving using sonic welding rather than screws to assemble component parts
- Sourcing of component parts—component part composition, component part supplier, or the use of a different component part from the sample supplier
- Tooling—equipment, machines, tools, dies, and cleaning solution tools on the production line
- Changes in manufacturing facility—different factory or factories

If any of these material changes could affect a product's ability to comply with a children's product safety rule, additional testing based on the material change is required and a new children's product certificate must be issued based on the new product. As previously noted, full testing may not be required.

Undue Influence

The *undue influence* requirement of **16 CFR 1107** is one that may require a new *formal policy* to be developed by the manufacturer. Each manufacturer must establish procedures to safeguard against the exercise of undue influence by a manufacturer on a third party lab. The procedure must include, at a minimum, safeguards to prevent attempts by the manufacturer to exercise undue influence on the third party lab, including a written policy statement from company officials that the exercise of undue influence is not acceptable. All appropriate staff members must receive training on avoiding undue influence and must sign a statement attesting to participation in such training. The undue influence policy must include a requirement for retraining if the policy is significantly changed. There must be a requirement to notify the *CPSC* immediately of any attempt by the manufacturer to hide or exert undue influence over test results, and a requirement to inform employees that allegations of undue influence may be reported confidentially to the CPSC, and how to do so. All of this must be documented.

Recordkeeping

Required documentation must be maintained for a period of 5 years, and they must be made available to the CPSC upon request, either in hard copy or electronically. The records can be maintained in languages other than English as long as they can be provided immediately to the CPSC upon request and can be translated accurately into English by the manufacturer within 48 hours of CPSC request. Some of the production testing plan components and factory QC records, for example, may be written in Chinese for the factory, and this is acceptable as long as they are available and can be promptly translated into English.

Summary

When taking into account the documentation requirements of various countries, one could have a single file that includes all of these appropriate documents.

Please keep in mind that testing requirements are not harmonized, resulting in many unique requirements for various countries such as the U.S. Undue Influence requirement and Europe's Safety Assessment and Safety Data Sheets.

While not mandatory for all items, the information included here is an important part of any compliance program. The manufacturer or supplier must know their product—what it is made of, how and where it was manufactured, compliance information, and more.

Technical File Required Documentation

Children's Product Certificate (CPC)

Separate CPCs and test records required for each manufacturing site

Certification Test Reports For Each Product

- Children's products require testing from a CPSC-approved third party test lab
- Annual Testing may be required
- General use products require testing as applicable per specific standards
- Corrective action plans should be documented if needed

Periodic Testing Plan

- Children's products require testing from a CPSC-approved third party test lab
- Periodic testing must include
 - Tests to be conducted
 - Intervals at which the tests will be conducted
 - Number of samples tested

Production Testing Plan

- May include
 - Internal/external test reports of recurring testing
 - Production test results
 - Periodic test results
 - Process management records
 - Controls charts
 - Statistical process control programs
 - Failure modes and effects analyses (FMEAs)
 - Factory quality control plans

Material Changes

- Records of any change in product's design, manufacturing process, or sourcing of component parts that may affect compliance
 - Certification tests on changed product or components as needed

Undue Influence

- Written policy with training records

Online Resources:

PPAI Product Responsibility: : <http://ppai.org/corporate-responsibility/product-responsibility/>

Technical File Procedures: http://www.export.gov/cemark/eg_main_017275.asp

PPAI Undue Influence Training: <https://onlineeducation.ppai.org/products/psa-required-undue-influence>

Recalls: www.recalls.gov

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